K032755

MAY 21 2004

## 510(K) SUMMARY

December 15, 2003

a. Applicant's Name and Address

Respironics Novametrix, Inc.
5 Technology Drive
Wallingford, CT 06492

b. Contact Person

Michael J. Malis
Q.A. and Regulatory Manager
(203) 697-6442
(203) 284-0753 (facsimile)

c. Name of Device

| | |
|---|---|
| Device Names (Proprietary/Trade Names): | Model 509M Pulse Oximeter |
| Device Name (Common Name): | Pulse Oximeter |
| Classification: | Class II, 21 C.F.R. 870.2700<br>74DQA/74 DPZ |

d. Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for the Model 509M, as well as testing to accepted industry standards. In addition, inter-device comparison studies were conducted to establish the Model 509Ms accuracy and to ensure that the sensors meet their currently published accuracy specifications with the Model 2001. The predicate device is as follows:

1. Model 2001 Pulse Oximeter, Novametrix Medical Systems, Inc., K993979,K000794)

e. Device Description

The Model 509M Pulse Oximeter Module is designed for continuous, non-invasive monitoring of the functional oxygen saturation of arterial hemoglobin ($SpO_2$) and pulse rate. Oxygen saturation is measured with ratiometric technique using red and infrared absorbance of oxy- and deoxyhemoglobin and pulse rate is measured using the time between successive pulses. The $O_2$ saturation sensors are already legally marketed as accessories to the Model 2001 monitor. The Model 509M displays digital values of $SpO_2$ and pulse rate and transmits these values as well as the plethysmogram to a Philips Monitoring System via the VueLink Interface. The Model 509M module consists of a dual microprocessor based data acquisition system that measures oxygen saturation data. The firmware for the primary microprocessor is responsible for handling the user interface and communications with external devices via VueLink interface. The firmware for the second microprocessor, a digital signal processor, performs the filtering, pulse rate and saturation calculations of the algorithms which analyze the incoming signals and perform noise reduction on that signal when the presence of noise is detected.

The Model 509M is powered by an external DC power supply. Audible and visual alarms for high/low saturation and pulse rate are available. Visual alerts are provided as a status message displayed on the Philips monitor's display (providing the alarms on the Philips dipslay are not disabled) The Model 509M also includes a temporary (2 minute) and permanent alarm silence and other configurable settings. The Model 2001 Pulse Oximeter has visual indicators for pulse error conditions, and alarm silence.

f. Intended Use

The Model 509M Pulse Oximeter is intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused in hospital, hospital-type facilities and intra-hospital transport environments such as the operating room, emergency department and intensive care units. The Model 509M Pulse Oximeter and its sensors are intended to be used by trained operators when pulse oximetry monitoring is required in the judgement of a physician. The intended use, patient population and environments of use are the same or similar to the predicate device, the Novametrix Model 2001.

g. Technological Characteristics

The Model 509M Pulse Oximeter measures functional oxygen saturation and pulse rate with sensors that contain red and infrared light sources. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation. The light energy from red and infrared LEDs is beamed through a sample cell- a pulsating vascular bed, the patient's finger or toe for example. The remaining light energy not absorbed by the sample cell reaches a photodiode, on the opposing side of the sensor. The signal received by the photodiode is split into its red and infrared components, sampled, software filtered, processed using proprietary algorithms and displayed as a numerical value for functional oxygen saturation and as a waveform, the plethysmogram.

The Model 509M uses the identical $SpO_2$ and pulse rate software algorithm to process the information from the sensor as the predicate device, Model 2001 Pulse Oximeter, cleared under K993979 and K000794.

h. Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

Respironics Novametrix, Inc. believes that all data and information submitted in this notice are truthful and accurate and no material fact has been omitted.

Michael J. Malis
Q.A. and Regulatory Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2004

Mr. Kevin Mader
Manager of Quality Assurance and Regulatory Affairs
Respironics Novametrix, Inc.
5 Technology Drive
Wallingford, Connecticut 06492

Re: K032755
Trade/Device Name: Model 509M Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DPZ
Dated: April 15, 2004
Received: April 19, 2004

Dear Mr. Mader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032755

Device Name: Model 509M Pulse Oximeter

**Indications For Use:**

The Model 509M Pulse Oximeter is intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused in hospital, hospital-type facilities and intra-hospital transport environments such as the operating room, emergency department and intensive care units.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/20/2004

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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